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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,953	03/01/2005	Noriaki Shimada	259788US0PCT	5052

22850 7590 03/27/2007
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/27/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/27/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/508,953

Applicant(s)

SHIMADA ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/04/04; 01/06/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by using passive voice (“characterized” and “maintained”) for recitation of the method steps. Thus, the claim is incomplete for omitting some essential active steps, such omission amounting to a gap between the steps by confusing what is actually manipulated and what are intended results/effects. See MPEP § 2172.01.

Claims 2 and 3 are rendered indefinite by the phrase “at least Lanford’s medium”. First, it is unclear what are the contents of the claimed “Lanford’s medium”. The medium composition disclosed by applicants on page 9 of the instant specification is different from all 3 media disclosed by Lanford et al., for example: see table 1 on page 175. (In Vitro Cellular and Developmental Biology. 1989. Volume 25, Number 2, pages 174-182.). Second, it is unclear what ingredients of the culture media are required and what are excluded by the phrase “at least” as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 08-009966 (IDS reference).

Claims are directed to a method for culturing hepatocytes for a long term by maintaining fresh hepatocytes at 15-30° C for 1-6 days followed by culturing under physiological conditions. Some claims are further drawn to the use of medium that contains at least some components the “Lanford’s medium”. Some claims are further drawn to culturing under physiological conditions or at about 37° C.

JP 08-009966 discloses a method for maintaining and/or culturing hepatocytes during transportation by maintaining and/or culturing fresh hepatocytes at 4-39° C embedded in a gel-containing medium. The temperature intervals are over-lapping. The contents of claimed medium are indefinite. Thus, the claimed method cannot be reasonably distinguished from the cited method. Therefore, the cited document is considered to anticipate the presently claimed invention.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Norio Kurihara et al. (Pesticides Biochemistry and Physiology. 1984. 21, 63-73).

Claims as above.

Norio Kurihara et al. discloses a method for maintaining or culturing fresh hepatocytes and measuring enzymatic activity of hepatocytes. The method comprises active steps of maintaining or culturing fresh hepatocytes at 20-25 ° C for 24-48 hours (see table 5 and page 69,

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col.2, par. 2, lines 8-10) followed by culturing at about 37° C for measuring enzymatic activity or metabolic reactions (table 5 and page 66, par. 2, line 6). The hepatocyte culture medium contains insulin and hydrocortisone (page 64, col. 2, par. 4) and, thus, "at least" some components the "Lanford's medium" (see specification page 9) within the meaning of the instant claims. The reference by Norio Kurihara et al. clearly teaches that viability and metabolic activity of isolated hepatocytes is maintained at 20 ° C while maintenance or culturing at 37 ° C causes rapid loss of metabolic activity (table 6). Therefore, the cited document is considered to anticipate the presently claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norio Kurihara et al. (Pesticides Biochemistry and Physiology. 1984. 21, 63-73) and JP 08-009966 (IDS reference) taken with Lanford et al. (In Vitro Cellular and Developmental Biology. 1989. Volume 25, Number 2, pages 174-182).

Claims are directed to a method for culturing hepatocytes for a long term by maintaining fresh hepatocytes at 15-30° C for 1-6 days followed by culturing under physiological conditions. Some claims are further drawn to the use of "Lanford's medium" for culturing hepatocytes. Some claims are further drawn to culturing under physiological conditions or at about 37° C.

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The cited reference by Norio Kurihara et al. and JP 08-009966 teach methods for maintaining and/or culturing hepatocytes at ambient temperature and under physiological conditions as explained above. The cited references are lacking particular disclosure about the use of the “Lanford’s medium” for culturing hepatocytes. But the reference by Lanford et al. teaches this medium (table 1, page 175) as intended for culturing fresh hepatocytes and for long-term maintenance of hepatocytes. The reference by Norio Kurihara et al. also teaches that viability and metabolic activity of isolated hepatocytes is maintained at 20 ° C while maintenance or culturing at 37 ° C causes rapid loss of metabolic activity (table 6).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to maintain fresh hepatocytes at low and/or ambient temperatures with a reasonable expectation of success in maintaining viability and metabolic activity of isolated fresh hepatocyte as clearly taught and/or suggested by Norio Kurihara et al. One of skill in the art would have been motivated to use the “Lanford’s medium” because it has been known and used for long-term primary cultures of hepatocytes as demonstrated by the cited prior art. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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March 16, 2007

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal line extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER